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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/284,147	03/17/1999	MICHEL LANQUETIN	GEI-067	1949

7590

04/23/2002

BIERMAN MUSERLIAN AND LUCAS  
600 THIRD AVENUE  
NEW YORK, NY 10016

EXAMINER
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QAZI, SABIHA NAIM

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 04/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/284,147	LANQUETIN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Sabiha Naim Qazi	1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 21 December 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 24,25,27-30,33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 3,24,25,27,33 and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

**Office Action on Merits**

Claims 24, 25, 27-30, 33 and 34 are pending and rejected.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Declaration filed in paper no. 19 and response in paper no. 20 is hereby acknowledged. Amendments are entered. Declaration and request for reconsideration were considered but was not found persuasive. In declaration the comparison is not a side-by-side comparison. See MPEP 716.02(e). Amount of compounds, which are compared, are different therefore, different results would be expected. Nomegesterol profile as shown is known for this compound, such as strong progestative activity, without androgenic effect, without estrogenic effect etc.

New rejection is as follows. Other rejections are maintained for the same reasons as set forth in our previous office action.

***Claim Rejections - 35 USC § 112***

Claims 24, 25, 27-30, 33 and 34 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Method claim 34 has no positive steps.

Citation of term "hypoestrogenism" is not in specification. It is suggested to replace with appropriate word used in the disclosure. What is the meaning of "functional disorders" in claim 34?

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patent ability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patent ability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claims 24, 25, 27-30, 33 and 34 are rejected under 35 U.S.C. 103(a) as obvious over Plunkett et al. (US Re. 36,247) and Fraser et al. (Medline, AN 89261206, abstract of Maturitas, (1989 Mar) 11(1), 21-34). Both the references teaches the art which embraces instantly claimed invention.

**1. Determining the scope and contents of the prior art.**

Plunkett teaches a method of hormonal treatment for menopausal disorders involving continuous administration of progestogens and estrogens. See the entire document especially lines 40-51, col. 2; lines 63-67, col. 2; lines 1-67, col. 3; lines 18-25, and lines 1-5, col. 4; lines 46-50, col 6.

The reference teaches continuous and uninterrupted administration of progestogen and estrogen. The actual unit dosage are selected according to conventionally known methods, e.g. body weight of patient and biological activity of hormones with the ultimate goal of producing the desired result with minimum quantities of hormones. It does not specifically discloses progestogen, nomegestrol acetate.

Fraser teaches the effects of the addition of nomegestrol acetate. All patients experienced a regular, progestogen-induced withdrawal bleed each month; and histological, ultra structural and biochemical changes were induced within the endometrium by all doses (0.5 mg, 1.0 mg; and 2.5 mg) is a potent progestogen. See the abstract.

**2. Ascertaining the differences between the prior art and the claims at issue.**

Instant claims are drawn to a method of treating deficiencies of estrogen by continuously administering a combination of estrogen and nomagesterol acetate.

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Plunkett et al differs from the instant invention in that it does not specifically name nomegesterol acetate however, Fraser teaches the advantages of using nomegesterol acetate.

**3. Resolving the level of ordinary skill in the pertinent art.**

Therefore, it would be obvious to one skilled in the art at the time of invention to prepare a composition to administer continuously combination of estrogen and nomegesterol as progestagen due to the advantages taught by the prior art. See as cited above.

**4. Considering objective evidence present in the application indicating obviousness or nonobviousness.**

Motivation is to use estrogen and progestogen continuously as taught by Plunkett et al. and use nomegesterol as progestagen because it gives in all patients regular, progestogen-induced withdrawal bleed each month; and histological, ultrastructural and biochemical changes were induced within the endometrium by all doses (0.5 mg, 1.0 mg; and 2.5 mg) is a potent progestogen. Thus, there has been ample motivation provided by the teachings of both the references cited above to prepare the instant invention in absence of any criticality or unexpected results.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

**Telephonic Inquiry**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Naim Qazi whose telephone number is 703-305-3910. The examiner can normally be reached on First Friday Off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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April 21, 2002



SABIHA QAZI, PH.D  
PRIMARY EXAMINER